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SYSTEMATIC REVIEW

Treatment of constipation-predominant irritable bowel syndrome by focusing on the liver in terms of Traditional Chinese Medicine: a meta-analysis

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Abstract

OBJECTIVE: To assess the efficacy of Traditional Chinese Medicine (TCM) on constipation-predominant irritable bowel syndrome by focusing on the liver.

METHODS: Databases (domestic and foreign) were searched with the key words "irritable bowel syndrome", "constipation", and "Chinese medicine"; the relevant articles were retrieved and evaluated. Cure rate, "remarkable efficacy", recurrence rate and the incidence of adverse reactions were the outcome indicators. Review Manager ver 5.1 was used for this meta-analysis, and funnel plots used to detect publication bias.

RESULTS: Nineteen randomized controlled trials were included and 1510 patients involved. The treatment guided by TCM based on the liver was superior to Western Medicine [odds ratio (*OR*) =2.46, 95% confidence interval (*CI*) 1.80, 3.35)], cure rate [*OR*=2.61, 95% *CI* (1.93, 3.52)], remarkable efficacy [*OR*=2.68, 95% *CI* (1.82, 3.95)], recurrence rate [*OR*= 0.19, 95% *CI* (0.12, 0.29)] and the incidence of adverse reactions [*OR*=0.24, 95% *CI* (0.09, 0.65)]. However, funnel plots showed publication bias.

CONCLUSION: Compared with Western Medicine, the treatment of IBS-C based on the liver is significantly better but the results must be treated with caution because publication bias was recorded.

Key words: Meta-analysis; Medicine, Chinese traditional; Constipation; Irritable bowel syndrome; Randomized controlled trial

INTRODUCTION

In recent years, the incidence of irritable bowel syndrome (IBS) in Western and Asian countries has been increasing, and has greatly affected people's quality of life (QoL).[1,2] Medical treatment is focused mainly on regulation of intestinal transit and visceral sensation, anxiolytics, and antidepressants. However, the "ideal" therapy for IBS has not yet been formulated.[3]

Traditional Chinese Medicine (TCM) may have some advantages in the treatment of IBS. Some systematic reviews have reported that TCM has effects against constipation-predominant irritable bowel syndrome (IBS-C) and diarrhea predominant irritable bowel syn-

drome (IBS-D).[4,5] In terms of TCM theory, Zhou *et al* [6] stated that the pathogenesis of IBS-C could be attributed to "deficiency" and "stagnation". Stagnation of liver *Qi* was considered to be the key factor and spleen deficiency another factor in the pathogenesis of IBS-C. Chen *et al* [7] categorized patients with IBS into three syndromes: stagnation of liver *Qi*; stagnation of liver *Qi* and spleen deficiency; and deficiency of liver *Qi* and *Yang*. They found that the syndrome of stagnation of liver *Qi* is more common in IBS-C or IBS with constipation and diarrhea alternating (IBS-A). The syndrome of stagnation of liver *Qi* and spleen deficiency is more common in IBS-D or IBS-A. The syndrome of deficiency of liver *Qi* and *Yang* is seen only in IBS-D.

Thus, dispersing stagnated liver *Qi* and regulating *Qi*-flow should be the key objectives when investigating the effect of treating IBS-C with TCM focusing on the liver.

METHODS

Chinese Biomedical Literature (CBM) database, China National Knowledge Infrastructure (CNKI) database and Pubmed were searched with the key words "irritable bowel syndrome" and "constipation" and "Chinese medicine". Five criteria were used. The first was that randomized controlled clinical trials (blinded or unblinded) were selected. The second criterion was that patients met the diagnostic criteria (international or national) for IBS-C. The third was that the TCM intervention involved Sini powder, Chaihushugan powder, Tongxieyao Fang, Xiaoyao powder as the basic recipes, or that prescribed recipes (including herbs having the effect of dispersing stagnated liver *Qi* and regulating *Qi*-flowing, e.g., Chaihu (*Radix Bupleuri Chinensis*), Baishao (*Radix Paeoniae Alba*), Zhiqiao (*Fructus Aurantii Submaturus*), Chenpi (*Pericarpium Citri Reticulatae*) or Xiangfu (*Rhizoma Cyperi*) were the primary or adjunct medicine. The fourth criterion was that the study included a comparison with Western Medicines, including intestinal prokinetic drugs, serotoninergic agents, antidepressants and anxiolytics. The final criterion was that the article was published between 1979 and October 2011.

The primary outcome was cure rate (main symptoms and primary symptoms), efficacy (main symptoms and primary symptoms) and other outcomes. The secondary outcomes were recurrence rate, symptom improvement, and safety (side effects and incidence of adverse reactions). Two reviewers assessed the quality of an individual study independently. If there was disagreement, the two reviewers discussed it to reach a consensus. If agreement was still not met, they sought help from a third party. The assessment was done following the "Risk of Bias" table (Figure 1), recommended in Cochrane Handbook 5.0. Studies were evaluated using the following items: (a) random sequence generation (selection bias); (b) allocation concealment (selection bias); (c) blinding of participants and personnel (performance bias); (d) blinding of outcome assessment (detection bias); (e) incomplete outcome data (attrition bias); (f) selective reporting (reporting bias); and (g) other types of bias.

The data extracted (Table 1) comprised general information regarding the study (first author, year of publication); nature of the study; general information about the participants; diagnostic criteria for IBS-C; sample size; intervention of the treatment group and control group; indicators of primary outcomes; indicators of secondary outcomes; course of treatment; and post-intervention indicators of improvement of symptoms. Review Manager (RevMan) (vers 5.1, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011) software was used for analyses. If the outcome of the heterogeneity test was not significant, a meta-analysis was done, and a fixed or random-effects model selected. Funnel plot analyses were undertaken to detect publication bias.

RESULTS

A total of 344 articles (337 in Chinese and 7 in English) were found. By excluding non-randomized controlled trials and duplicates, 116 articles (115 in Chinese and 1 in English) were available. After further review, we excluded trials that were not conducted with TCM treatment based on the liver, and those in which the subjects were not constipated. Then, 19 articles (18 in Chinese and 1 in English) were eligible for the analysis.

Among them, the biggest sample size was 129 and the smallest 47 (mean, 79) and 1510 subjects were involved. In 3 of the 19 studies, IBS-C was diagnosed with the criteria stated in Practical Medicine,[8-10] 1 with the IBS criteria colloquium on chronic diarrhea of China formulated in the 1986,[11] 1 with Rome criteria,[12] 12 with Rome II[13-24] and 2 with Rome III.[25,26]

TCM interventions in the 19 articles were mainly Chinese herbal compounds. None of them used a single herb or Chinese patented medicine for treatment. All 19 studies used TCM formulas with the effect of dispersing stagnated liver *Qi* and regulating *Qi*-flow. Western Medicine interventions in the 19 studies were: (a) prokinetic drugs (15 articles): 11 were compared with cisapride,[8,10-12,14-18,22,24] 2 with trimebutine,[9,23] 1 with mosapride[21] and 1 with tegaserod;[19] and (b) laxatives (4 articles): all were compared with polyethylene glycol.[13,20,25,26] Details of the randomized controlled trials included in the analysis are shown in Table 1.

Of the 19 studies, 12 used cure rate (recent cure rate) as the best outcome indicator[11,13,14,16,17,19-23,25,26] and 7 used "remarkable efficacy".[8-10,12,15,18,24] Nine studies showed that symptoms improved, but only 2 of them provided mean values and variance of the integration difference before and after treatment.[19,25] Eight of the studies reported the recurrence rate 3-6 months after the trial.[8,10,12,15,16,22,24,26] Six studies reported on the incidence of ad-

Table1 Variables extracted from included randomized controlled trials

General information	Nature of study	Diagnostic criteria of IBS-C	Indicators of improvement of post-intervention symptoms	Sample size	Intervention		Indicators of primary outcomes	Indicators of secondary outcomes	Course (weeks)
					TG	CG			
Cai W 2005[16]	RCT	Rome II	Efficacy	TG *n*=60; CG *n*=30	Self-prescribedrecipe (dispersing stagnated liver *Qi* to harmonizestomach) *q.d.*	Cisapride (5 mg, *t.i.d.*)	Efficacy: TG=83.3%; CG=70.0%	RR TG=12.0%, CG=42.9%	4
Chen TJ 2010[25]	RCT	Rome III	CR, efficacy, symptom scores+QoL scores	TG *n*=50; CG *n*=50	Self-prescribedrecipe (modifying liver *Qi*, regulating spleen *Qi* and purging)	Polyethylene glycol (20 g, *q.d.*)	CR: TG=36%, CG=16% Efficacy: TG=94%, CG=78%	Symptom scores: TG=-8.7±1.9, CG=-6.7±4.7; QoL scores: PF:TG (75±11,83±9), CG (77±9,80±10); RP:TG (48±16, 68±23), CG (47±9, 52±12); BP: TG (35±7, 64±7), CG (34±13, 57±10); GH: TG (35±12, 65±13), CG (34±7, 62±14); VT: TG (37±6, 57±7); CG (43±10, 53±10); SF: TG (45±10, 67±14), CG (45±11, 57±15); RE: TG (44±20, 69±15); CG (40±18, 43±18); MH:TG (33±6, 58±8); CG (35±8, 52±10); RR and IAR not mentioned	4
Chen XG 2005[15]	RCT	Rome II	Efficacy+symptom scores	TG *n*=41; CG *n*=37	Yiji-II (*q.d.*)	Cisapride (5 mg, *t.i.d.*)	Efficacy: TG=92.7%, CG=73.0%	IAR not found	4
Cui WQ 2007[9]	RCT	Practical Internal Medicine	Efficacy+symptom scores	TG *n*=32; CG *n*=30	Modified Jieyu Runchang soup (*q.d.*)	Trimebutine (0.1 g, *t.i.d.*)	Efficacy: TG=87.5%, CG=73.4%	RR, symptom improvement and safety indicators not mentioned	4
Ding Y, Mao SQ 2010[23]	RCT	Rome II	Efficacy+symptom scores	TG *n*=64; CG *n*=60	Modified Piwei Xiaoyao powder (*q.d.*)	Trimebutine (0.2 g, *t.i.d.*)	Efficacy: TG=90.63%, CG=76.63%	IAR not found	4
Du GY, Zheng SK 2006[13]	RCT	Rome II	CR efficacy	TG *n*=32; CG *n*=30	Sini powder mixed with Wuren soup (*q.d.*)	Polyethylene glycol (10 g, *b.i.d.*)	CR: TG=68.8%, CG=40.0% Efficacy: TG=93.8%, CG=70.0%	IAR not found	8
Hu HF 2006[14]	RCT	Rome II	Efficacy	TG *n*=57; CG *n*=33	Jianpi Daozhi soup (*q.d.*)	Cisapride (10 mg, *t.i.d.*)	Efficacy: TG=91.23%, CG=87.88%	2 in TG suffered from diarrhea, 2 in CG suffered from IAR	4

General information	Nature of study	Diagnostic criteria of IBS-C	Indicators of improvement of post-intervention symptoms	Sample size	Intervention		Indicators of primary outcomes	Indicators of secondary outcomes	Course (weeks)
					TG	CG			
Hu K 2006[17]	RCT	Rome II	CR, efficacy+plasma levels of somatostatin and vasoactive intestinal peptide	TG *n*=40; CG *n*=20	Modified recipe of Shugan Runchang (*q.d.*)	Cisapride (10 mg, *t.i.d.*)	CR:TG=85%, CG=60%; Efficacy: TG=92.5%, CG=90%; VIP: TG=204.25±16.21, CG=302.73±17.3; SS: TG=21.7±8.03, CG=62.6±11.3	RR, symptom improvement and safety indicator not mentioned	4
Liu JX 2006[19]	RCT	Rome II	CR, efficacy + symptom scores	TG *n*=32; CG *n*=33	Modified Sinisan (*q.d.*)	Tegaserod (6 mg, *b.i.d.*)	CR: TG=31.25%, CG=33.33% Efficacy: TG=71.88%, CG=72.72%	Abdominal pain: TG (1.55±0.58, 0.84±0.55), CG (1.64±0.57, 0.6±0.33); Constipation: TG (2.43±0.33, 1.07±0.22), CG (2.34±0.31, 0.59±0.22); Diarrhea: TG (0,0.82±0.53), CG (0,1.69±0.43); Vertigo: TG (0,0), CG (0,0.53±0.24) RR and safety indicator not mentioned	4
Liu JH, Chen Y 2010[24]	RCT	Rome II	RE, efficacy instantly and 6 months later	TG *n*=40; CG *n*=36	Self-prescribed Huanji Tongbian soup	Cisapride (5 mg, *t.i.d.*)	RE: TG=45%, CG=38.9% Efficacy: TG=87.5%, CG=88.9%	RR 6 months later; TG=11.4%, CG=59.4% Symptoms improvement and IAR not mentioned	8
Lu XF, Chen BC 2008[22]	RCT	Rome II	Efficacy+symptom scores	TG *n*=96; CG *n*=48	Yimu Hezhong soup (*q.d.*)	Cisapride (10 mg, *t.i.d.*) Doxepin (25 mg *t.i.d.*)	Efficacy: TG=91%, CG=88%	IAR did not occur in TG; RR: RR (3 months later) TG=14%, CG=19%; RR (6 months later) TG=17%, CG=31%	8
Wang KP 2004[11]	RCT	IBS criteria formulated on the 1986 Colloquium on Chronic Diarrhea in China	CR+efficacy	TG *n*=36; CG *n*=30	Self-prescribed recipe (dispersing stagnated liver *Qi*, regulating *Qi* flow and nourishing the bowel)	Cisapride (10 mg, *t.i.d.*)	CR: TG=69.44%, CG=26.67% Efficacy: TG=91.67%, CG=73.33%	RR, symptom improvement and safety indicator not mentioned	3
Wu WQ 2007[21]	RCT	Rome II	CR+efficacy	TG *n*=52; CG *n*=52	Self-prescribed recipe (dispersing stagnated liver *Qi* and regulating *Qi* flow)	Mosapride (5 mg, *t.i.d.*)	CR: TG=65.38%, CG=30.77% Efficacy: TG=96.15%, CG=80.77%	RR, symptom improvement and safety indicator not mentioned	4

General information	Nature of study	Diagnostic criteria of IBS-C	Indicators of improvement of post-intervention symptoms	Sample size	Intervention		Indicators of primary outcomes	Indicators of secondary outcomes	Course (weeks)
					TG	CG			
Xiang AM 2007[10]	RCT	Practical Internal Medicine	Short-term and long-term efficacy+symptom scores	TG *n*=30; CG *n*=30	Modified Simo soup mixed with Xiaoyao powder (*q.d.*)	Cisapride (5 mg, *t.i.d.*)	Efficacy: TG=93.33%, CG=63.33% Efficacy: TG=83.33%, CG=40.0%	RR: TG=10.7%, CG=26.3%	8
Yu SP 2005[12]	RCT	Rome	RE, Efficacy, symptom scores and pressure on anus and rectum	TG *n*=24; CG *n*=23	Modified Sinisan (*b.i.d.*)	Cisapride (10 mg, *t.i.d.*)	RE: TG=83.33%, CG=56.52% Efficacy: TG=95.83%, CG=78.26%	Difference in symptom scores: TG=12.21±5.34; CG=4.42±4.57 RR (6 months later): TG=4.35%; CG=55.56% IAR not mentioned	8
Zhang JH 2004[8]	RCT	Practical Internal Medicine	RE, efficacy instantly and 6 months later	TG *n*=36; CG *n*=32	Self-prescribed Tongbian soup (regulating *Qi* flow and purging)	Cisapride (5 mg, *t.i.d.*)	RE: TG=44.4%, CG=37.5% Efficacy: TG=88.8%, CG=90.6%	RR: RR (3 months later) TG=12.5%, CG=58.6%; RR (6 months later) TG=17%, CG=31% Symptom improvement and IAR not mentioned	8
Zhang JJ 2010[26]	RCT	Rome III	CR efficacy, TCM symptom scores and efficacy 3 months later	TG *n*=40; CG *n*=40	Self-prescribed Tongbian soup (harmonizing liver and spleen; 200 mL, *b.i.d.*)	Polyethylene glycol (10 g, *b.i.d.*)	CR: TG=7.50%, CG=2.50% Efficacy: TG=95%, CG=92.5%	RR: RR (3 months later) TG=5.26%, CG=32.43%; TCM symptom scores: TG (15.68±1.82, 8.61±3.27), CG (15.71±1.94, 10.96±3.51); IAR occurred in 1 case of TG and disappeared when dose was halved whereas 4 occurred in CG and disappeared without treatment	12
Zhang T 2003[18]	RCT	Rome II	RE+efficacy	TG n=42; CG n=20	Self-prescribed recipe (dispersing stagnated liver *Qi* and nourishing the bowel; *q.d.*)	Cisapride (10 mg, *t.i.d.*)	RE: TG=76%, CG=40% Efficacy: TG=100%, CG=70%	RR, symptom improvement and safety indicator not mentioned	4
Zhao RL, Fang J 2007[20]	RCT	Rome II	Efficacy+symptom scores	TG *n*=36; CG *n*=36	Modified Erhe soup (*q.d.*)	Polyethylene glycol (10 g, *b.i.d.*)	Efficacy: TG=100%, CG=97.2%	RR, symptom improvement and safety indicator not mentioned	4

Notes: CG: control group; TG: treatment group; RCT: randomized controlled trial; CR: cure rate; RE: remarkable efficacy; RR: recurrence rate; IAR: incidence of adverse reactions; PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health; HT: health transition.

verse reactions,[13-15,22,23,26] 2 of which reported no adverse reactions.[22,23] Three studies used health-related QoL scores as well as the plasma level of somatostatin and vasoactive intestinal peptide as outcome indicators.[22,23] Upon consideration of the combined effect as well as the statistical effect, then cure rate, remarkable efficacy, general efficacy, recurrence rate and incidence of adverse reactions were used as outcome indicators.

All 19 articles mentioned "randomization" and reported the baseline characteristics and statistical differences with regard to sex, age and disease course between the treatment group and control group, but only 2 of the studies mentioned the specific method of randomization. Only 1 of the articles reported patient withdrawal from the study and its cause. None of the articles mentioned allocation concealment or blinding. In sum, the studies were not rigorous, and the overall bias was quite considerable (Figure 1).

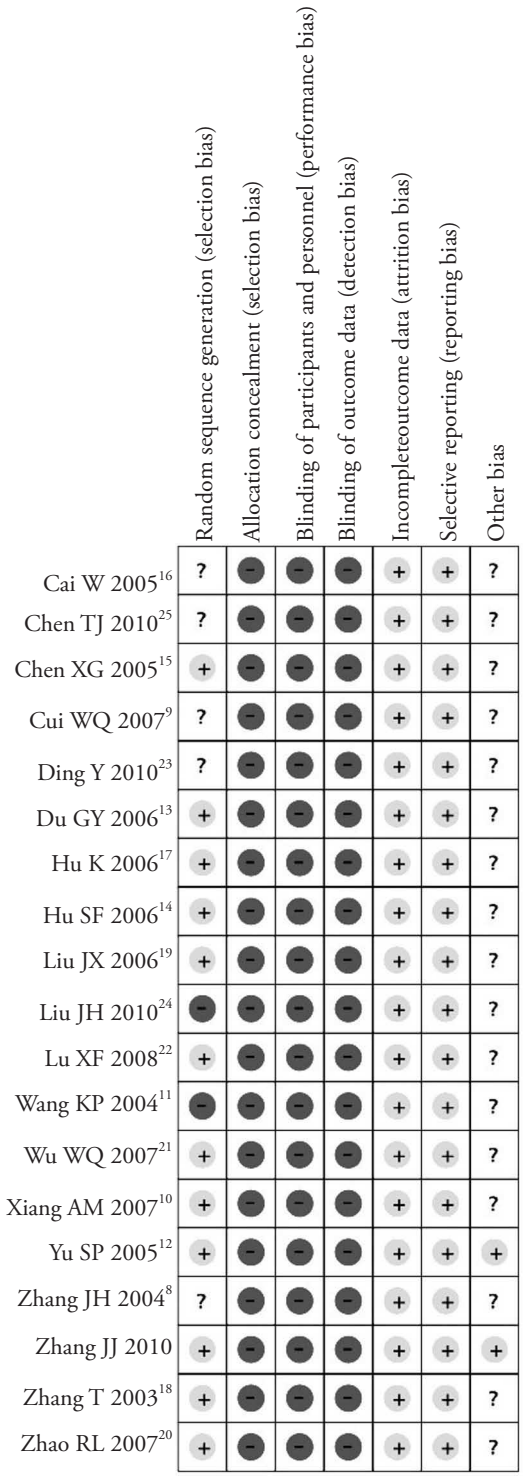

Figure 1 Risk of bias

Efficacy evaluation

In 1510 patients, 840 received TCM and 670 were treated with Western Medicine. The outcomes showed that the efficacy of TCM treatment based on the liver was significantly higher than that of Western Medicine (Figure 2).

Of the 12 studies that used cure rate as the best indicator of outcome, 1057 patients (595 received TCM treatment and 462 were treated with Western Medicine) were involved. The outcomes showed that the cure rate and remarkable efficacy of TCM treatment based on the liver were significantly higher than those of Western Medicine (Figures 3, 4).

In the 8 studies that focused on recurrence rate, 556 patients (331 received TCM medication and 225 were treated with Western Medicine) were involved. The outcomes showed that the recurrence rate of TCM treatment based on the liver was significantly lower than that of Western Medicine (Figure 5).

In the 6 studies that focused on adverse reactions, 578 patients (330 received TCM treatment and 248 were treated with Western Medicine) were involved. The outcomes indicated that the incidence of adverse reactions of TCM treatment based on the liver was significantly lower than that of Western Medicine (Figure 6).

Figures 7-11 display the outcomes of funnel plots. The analyses showed that there was a possible publication bias inherited from the studies.

DISCUSSION

Treatment based on the liver is an important method for IBS intervention in TCM. In terms of TCM theory, the liver controls conveyance and dispersion, and stores blood. "What governs conveyance and dispersion is the liver".[27] If *Qi* movement is obstructed, the stomach and spleen *Qi* would not function optimally, which would cause abdominal pain, imbalance of fluid diffusion, dryness of the bowel, and disorder of bowel function. These effects would lead to abdominal pain and constipation. Henningsen and colleagues[28] reviewed articles on Medline and PsycLIT/PsycINFO related to medically unexplained physical symptoms. They found that four functional somatic syndromes (including IBS) were related to depression and anxiety. This emotional disturbance would further affect liver *Qi* and formed a vicious cycle of effects.

TCM medications based on the liver that are commonly used for treating IBS-C are Sini powder, Chaihushugan powder, Xiaoyao powder and Tongxieyao Fang. Sini powder comprises Chaihu (*Radix Bupleuri*

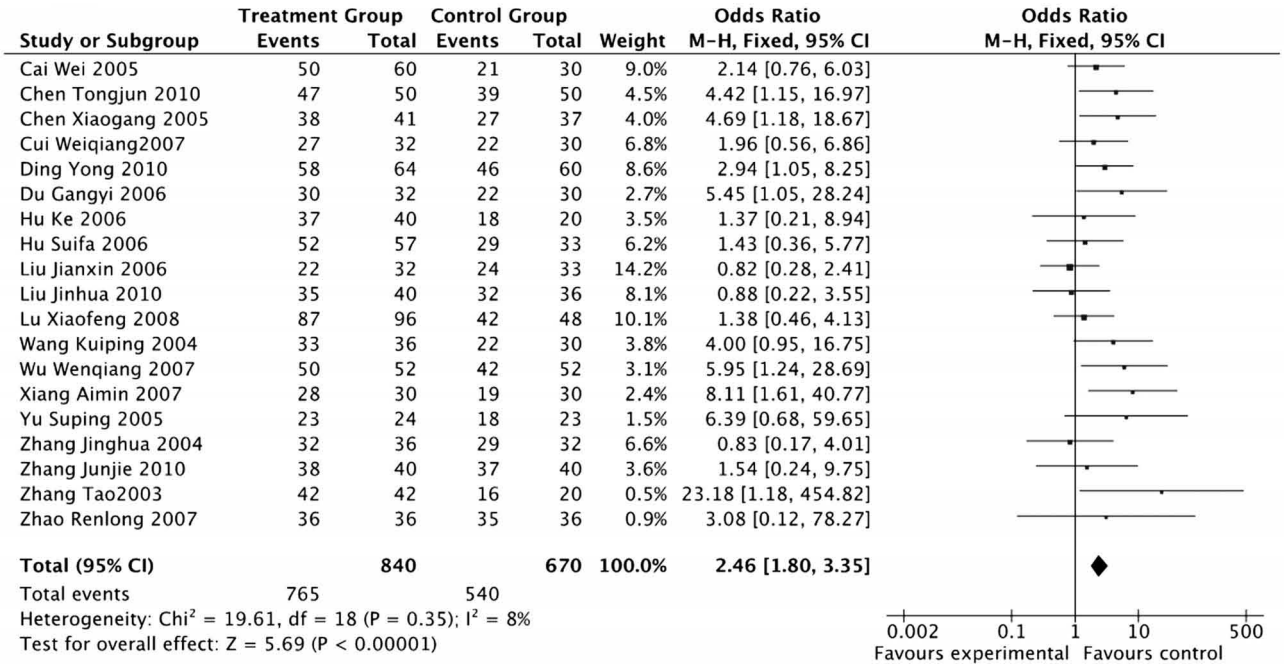

Figure 2 Difference in efficacy between TCM and Western Medicine

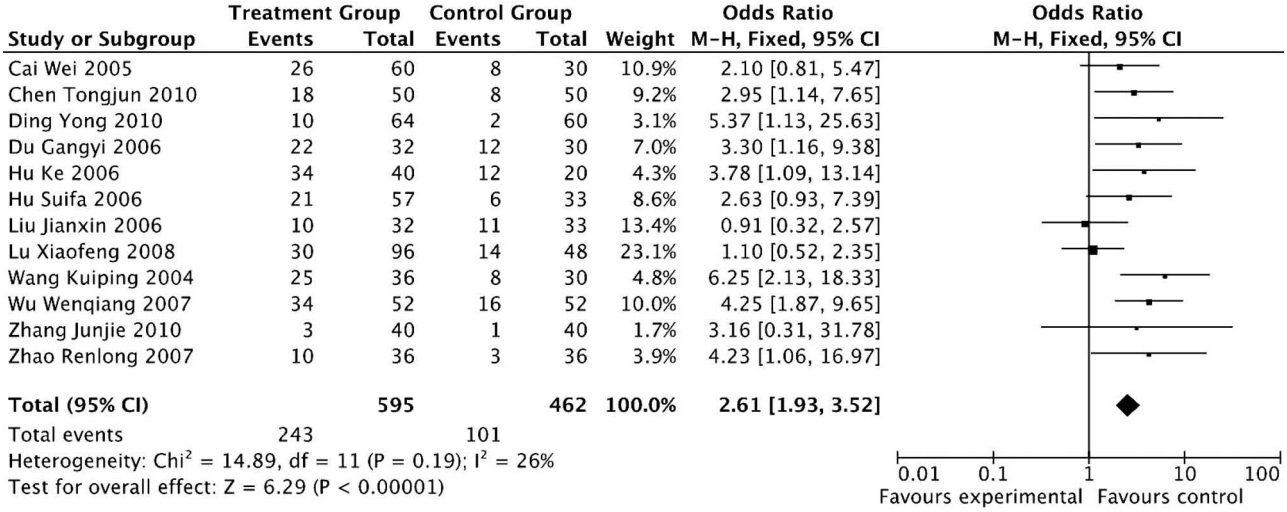

Figure 3 Difference in cure rate between TCM and Western Medicine

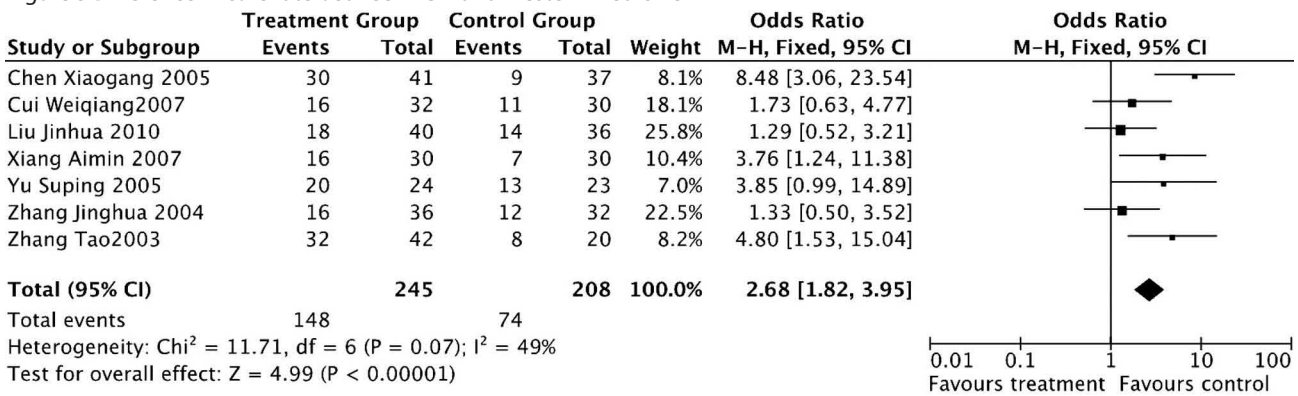

Figure 4 Difference in efficacy between TCM and Western Medicine

Chinensis), Zhishi (*Fructus Aurantii Immaturus*), Baishao (*Radix Paeoniae Alba*) and Gancao (*Radix Glycyrrhizae*). It is used mainly to treat the stagnation of *Yang* as well as *Qi* stagnation of the liver and spleen.[29] Chaihushugan powder is derived from Sini powder in that Zhishi (*Fructus Aurantii Immaturus*) is replaced with Zhiqiao (*Fructus Aurantii Submaturus*), and Chuanxiong (*Rhizoma Chuanxiong*), Chenpi (*Pericarpium Citri Reticulatae*) and Xiangfu (*Rhizoma Cyperi*) are added to enhance the effect of dispersing stagnated liver *Qi* and promoting blood flow to relieve pain.[30] Xiaoyao powder consists of Chaihu (*Radix Bupleuri Chinensis*), Danggui (*Radix Angelicae Sinensis*), Baishao (*Radix Paeoniae Alba*), Baizhu (*Rhizoma Atractylodis Macrocephalae*), Gancao (*Radix Glycyrrhizae*), Fuling (*Poria*), Bohe (*Herba Menthae Haplocalycis*) and Paoji-

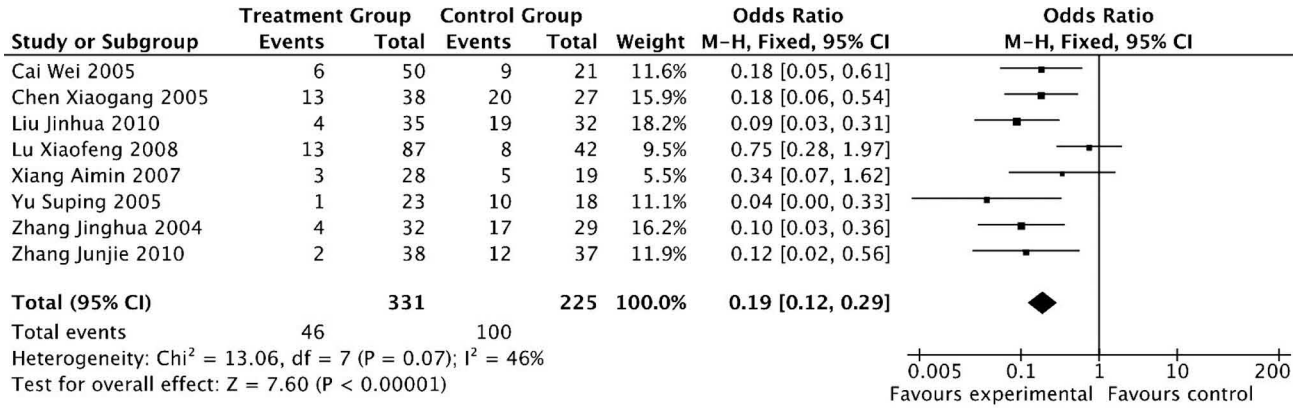

Figure 5 Difference in recurrence rate between TCM and Western Medicine

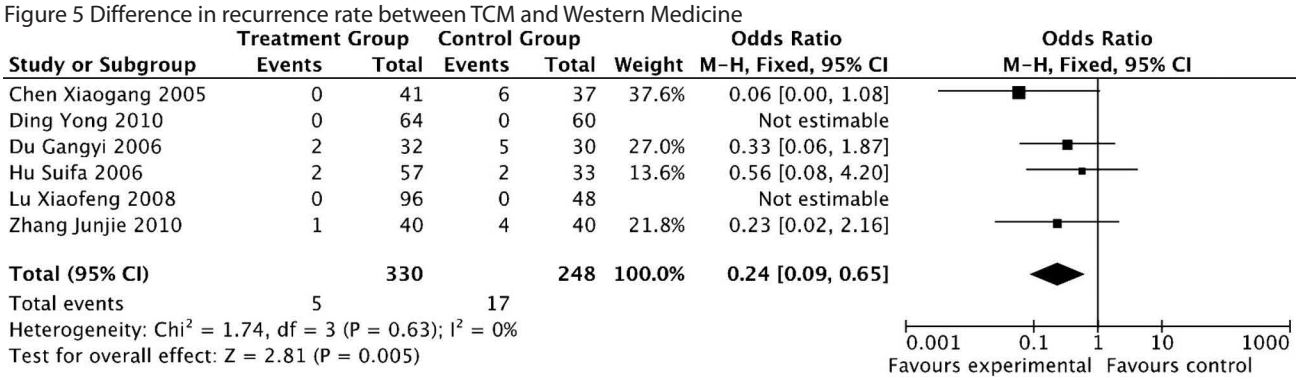

Figure 6 Difference in the incidence of adverse reactions between TCM and Western Medicine

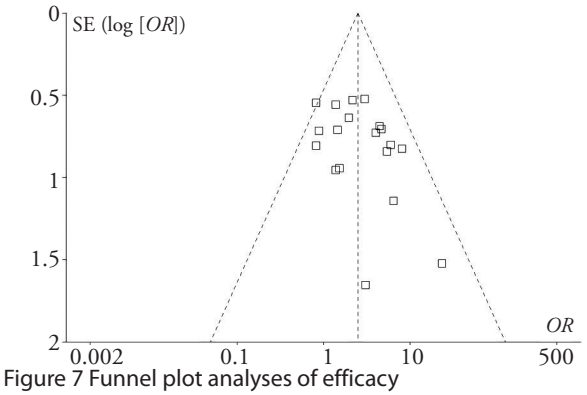

Figure 7 Funnel plot analyses of efficacy

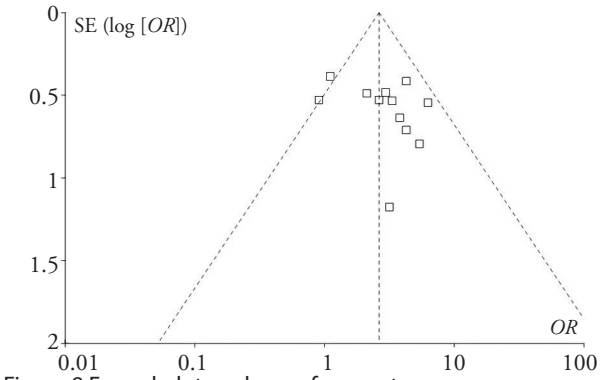

Figure 8 Funnel plot analyses of cure rate

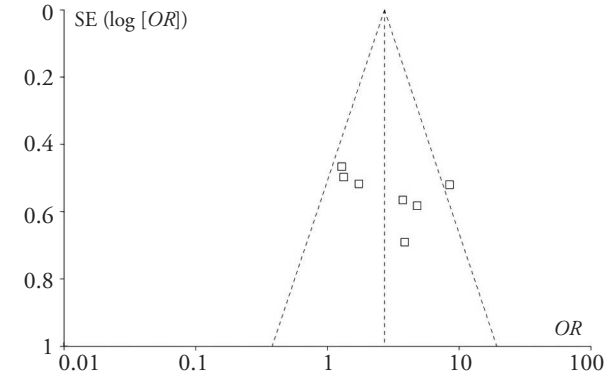

Figure 9 Funnel plot analyses of remarkably efficacy

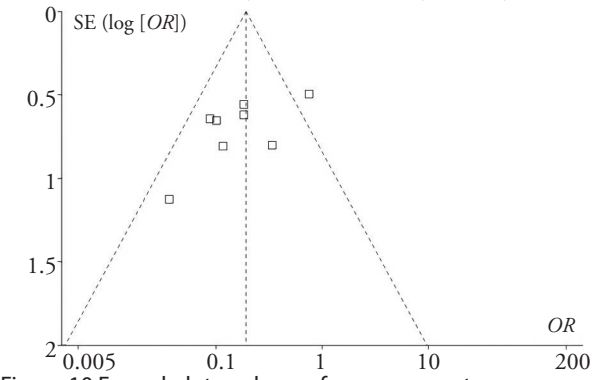

Figure 10 Funnel plot analyses of recurrence rate

ang (*Rhizoma Zingiberis Praepararum*). It can invigorate the spleen to eliminate dampness. Baizhu (*Rhizoma Atractylodis Macrocephalae*) and Fuling (*Poria*) can regulate the liver, spleen, blood and *Qi* simultaneously.[31] Tongxieyaofang is composed of Baizhu (*Rhizoma Atractylodis Macrocephalae*), Fangfeng (*Radix Saposhnikoviae*), Chenpi (*Pericarpium Citri Reticulatae*) and Baishao (*Radix Paeoniae Alba*).[32] It is a common basic recipe for treating diarrhea caused by disharmony between the liver and spleen, and is usually used to treat IBS-D. However, it has been reported that a combination of Tongxieyaofang and modified Sini powder can significantly worsen symptoms in patients with IBS-C or IBS-D.[33]

Our results provided evidence for the clinical application of the TCM theory that "the liver controls conveyance, dispersion, stores blood, and is closely connected to the spleen and stomach". However, the present meta-analysis had limitations. The included studies were not rigorous; the outcome indicators — efficacy, cure

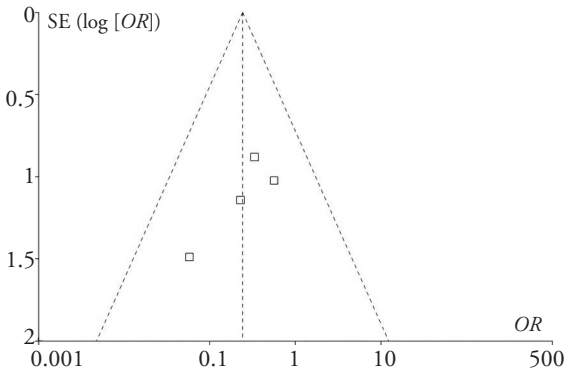

Figure 11 Funnel plot analyses of the incidence of adverse actions

rate, and remarkable efficacy — were not consistent. Hence, the placebo effect could not be ruled out.

In conclusion, the findings derived from the treatment of IBS-C with TCM based on the liver revealed that TCM intervention was significantly better than Western Medicine in terms of cure rate, remarkable efficacy, recurrence rate, and safety. However, because of the limitations inherited from the studies included in the analyses, these findings should be viewed with caution.

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